



CPR_x LLC

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October 23, 2002

Hina Patel, PhD
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850-3223

Re: Public Disclosure Submission for IDE #980125

Dr. Patel:

21 CFR 812.47 (a) requires the sponsor, when they receive information from the IRB concerning the public disclosures under Sec. 50.24(a)(7)(ii) and (a)(7)(iii), to submit to the IDE file and to the Dockets Management Branch, copies of the information that was disclosed. CPR_x has received copies of IRB information concerning the public disclosure that occurred and is forwarding them now to the IDE file and to the Dockets Management Branch.

Please feel free to contact me at 952-947-9570 or tprovo@resqcpr.com if you have further questions.

Sincerely,

Terry Provo
Director of Clinical Trials

958.0158

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